Structural, Non-Valvular Intervention

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TCT-81

Long-term Safety and Efficacy of Percutaneous Left Ventricular Transapical Access and Closure for Structural Heart Disease Interventions

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Background: Percutaneous transapical left ventricular (LV) access has been used for diagnostic and hemodynamic assessment of heart disease and more recently, for a multitude of interventional procedures. Common structural heart procedures that have benefited from this approach include the closure of paravalvular leaks (PVL), ventricular septal defects (VSD), and LV pseudoaneurysms (LVPA). Direct transapical puncture and device closure of the LV access site have demonstrated acute feasibility and safety with low complication rates. However, the long-term safety and efficacy of transapical access and closure have not been evaluated.
Methods: We evaluated patients at our center, from March 2008 to October 2011, who underwent structural heart disease interventions via a percutaneous transapical approach, were at least 6 months from their procedure and received a 6-4mm Amplatzer Ductal Occluder for closure. Follow-up 2-D/3-D transthoracic echocardiography (TTE) was performed in all patients. Cardiac computed tomographic angiography (CTA) with retrospective ECG-gated multiphase reconstruction was performed if TTE views were limited.
Results: A total of 10 patients were included (7 PVLs, 1 VSD, 2 LVPA). Mean time of procedure to follow-up imaging study was 10.1±2.9 months. In all 10 patients, there were no changes to the LV myocardium, the device, or the lungs and no pericardial or pleural effusions were noted. There were no LVPA at the puncture site or new wall motion abnormalities. In 2 patients, an apical wall motion abnormality was observed around the closure device. However, this was unchanged from the pre-procedural TTE and occurred in the setting of ventricular pacing. The devices were stable in location and exhibited no evidence of erosion, calcification, or thrombus formation. In the 9 patients in whom a CTA was performed, there was no evidence of left lung scarring or other pathology.
Conclusions: Early experience of long-term follow-up of left ventricular transapical access and closure demonstrates that using an Amplatzer Ductal Occluder can be safe and reliable, without evidence of structural abnormalities. Further evaluation of the long-term safety and efficacy of transapical closure is necessary.

TCT-82

Cost-effectiveness Of Transcatheter Left Atrial Appendage Occlusion Compared With 5 Alternative Anticoagulation Strategies For Stroke Prevention In Atrial Fibrillation: A Markov Decision Analysis

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Background: Transcatheter left atrial appendage (LAA) closure is a promising therapy to prevent stroke in patients with atrial fibrillation (AF). We aim to estimate the lifetime cost-effectiveness of LAA occlusion for preventing stroke in patients with non-valvular AF.
Methods: A Markov decision analytic model was used to compare cost-effectiveness of LAA occlusion device with 5 alternative anticoagulation strategies: aspirin alone, aspirin and clopidogrel, warfarin, dabigatran 150mg or 110mg. The model simulates a cohort of 65-year-old patients with AF moving between different health status in each Markov cycle of 1 year. The time horizon was lifetime (85 years old). Health states included AF without event, ischemic stroke, transient ischemic attack, hemorrhage, myocardial infarction, death from vascular cause, and death from any causes. Outcome measures are quality-adjusted life years (QALYs), lifetime costs and incremental cost-effectiveness ratios (ICERs). Base-case values for analytic model were derived from published references including the ACTIVE trial, RE-LY trial and PROTECT trial. One way sensitivity analysis varied by CHADS2 score and probabilistic sensitivity analyses using Monte Carlo simulations were conducted to assess parameter uncertainty. All costs are expressed in US dollars from US healthcare provider perspective.
Results: Compared with aspirin alone, LAA occlusion was cost-effective with an ICER of US$975 per QALY gained. Sensitivity analysis demonstrated progressive reduction in ICERs of LAA occlusion against aspirin for patient with increasing CHADS2 score of 0, 1, 2, 3, and ≥4 ($1,257, $1,104, $894, $626 and $518, respectively). LAA occlusion was the dominant strategy (i.e. less costly and more effective) compared with warfarin, aspirin and clopidogrel and dabigatran 100mg or 150mg for all patients irrespective of CHADS2 score. LAA occlusion device was cost-effective over 95% of the Monte Carlo simulation using a cost-effectiveness threshold of US$50,000 per QALY gained.
Conclusions: Transcatheter LAA occlusion is considered a cost-effective strategy compared with aspirin, aspirin and clopidogrel, warfarin, dabigatran 150mg or 110mg for stroke prevention in patients with AF.

TCT-83

Watchman Left Atrial Appendage Closure in Atrial Fibrillation Patients with Contraindication to Oral Anticoagulation: the "Aspirin Plavix Registry" (ASAP)

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Background: AF patients at the highest risk for embolic stroke also experience the greatest risk of hemorrhagic complications of anticoagulant use. The PROTECT AF trial revealed that LAA closure using the Watchman device was non-inferior to Warfarin for preventing stroke in AF pts with CHADS2 ≥ 1. However, these pts were treated with Warfarin post-implant until a TEE demonstrated LAA closure at 6 wks. Due to the pressing need for strategies that can prevent stroke in pts with contraindications to Warfarin, we performed a prospective study of Watchman implantation in Warfarin-contraindicated pts.
Methods: Prospective registry of pts with non-valvular AF, a CHADS2 score ≥1, and a contraindication to Warfarin use. The Watchman device was implanted in standard fashion. Post-implant, patients were discharged on 6 mo of clopidogrel and life-long aspirin. Follow-up TEE was performed at 3/12 months.
Results: At 4 centers, 150 pts were enrolled. The mean age was 72.5 ± 7.4 yrs. The prevalence of stroke risk factors was: CHF in 29%, HTN in 95%, Age ≥ 75 in 43%, DM in 32%, and stroke/TIA in 41%. The mean CHADS2 score was 2.8 ± 1.2. The reason for Warfarin contraindication was: hemorrhagic tendencies (26%), blood dyscrasias (7%), bleeding tendencies (67%), unsupervised pts with senility/high fall risk (4%), and other (5%). Watchman implantation was successful in 95% (142/150). At 14.2 ± 8.7 mo of follow-up, there were 4 strokes (3 ischemic) and 6 instances of device-related thrombus by TEE. The observed rate of ischemic stroke 1.7% represents 77% fewer events from that expected in pts with a similar CHADS2 score treated with aspirin alone (7.3%; Figure). Data from additional follow-up (to a total of >250 pt-yrs) will be available.
Conclusions: Watchman implantation without a Warfarin transition is safe and effective in AF pts with contraindications to even short-term oral anticoagulation.

TCT-84

Watchman Left Atrial Appendage Closure in Atrial Fibrillation Patients 75 years or Greater; A Sub-Analysis of the PROTECT AF Study

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Background: Left atrial appendage (LAA) closure is an important alternative to long term anticoagulant therapy for atrial fibrillation patients who are at high risk for stroke. As the risk of stroke and major bleeding from anticoagulation therapy increases in patients 75 years and older, we evaluated the long term effects of LAA closure vs. anticoagulation therapy of this age subgroup from the PROTECT AF trial.
Methods: Subjects in the PROTECT AF trial who were 75 years of age and older at the time of enrollment were compared via proportional hazards models for the following outcomes post-randomization: the composite primary efficacy endpoint (stroke, systemic embolism, and cardiovascular/unknown death), stroke, and all-cause mortality. The outcomes are expressed as a percent of subjects experiencing the event per year. The analysis compared the randomized intent-to-treat group and the post-procedure group to evaluate outcomes after risk associated with the implant procedure.
Results: There were 305 subjects age > 75 randomized in the study. The average follow-up was 27 months. For the composite primary efficacy endpoint, the intent-to-treat rate was 4.1%/y for the device group and 6.2%/y for the warfarin group (HR=0.65, 95% CI 0.33–1.30). Post-procedurally the primary efficacy endpoint rates were 3.6%/y and 6.2%/y for the device and warfarin groups, respectively (HR=0.58, 95% CI 0.28-1.18). The rates of stroke in were 3.1%/y and 4.3%/y for the device and warfarin groups (HR=.72, 95% CI 0.32-1.62) for intent-to-treat, and 2.6%/y and 4.3%/y in the post procedure group (HR=0.61, 95% CI 0.26-1.43). All-cause mortality rates in this age group were 5.2%/y and 5.7%/y for the device and warfarin groups, respectively (HR=0.89, 95% CI 0.46-1.72).
Conclusions: Patients > 75 years demonstrated a lower risk of primary efficacy (stroke, systemic embolism, and cardiovascular/unknown death), stroke and all-cause mortality with LAA closure than warfarin therapy. These results may confirm LAA closure with the WATCHMAN device as a reasonable alternative to anticoagulation for patients > 75 years of age.